

Amendment No. 1 to SB0475

Johnson  
Signature of Sponsor

**AMEND Senate Bill No. 475\***

**House Bill No. 614**

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. This act shall be known and may be cited as the "Opioid Baby Primary Prevention Act."

SECTION 2. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

(a) As used in this section:

(1) "Bureau" means the bureau of TennCare;

(2) "Comptroller" means the comptroller of the treasury;

(3) "Managed care organization" or "MCO" means a health maintenance organization, behavioral health organization, or managed health insurance issuer that participates in the TennCare program;

(4) "Pay for success program" or "PFS program" means a results-based public-private contract arrangement with a prevention service contractor who delivers a specific measurable intervention that has independently verifiable cost prevention savings within a defined population to solve a specific problem;

(5) "Pay for success savings formula" means a mathematical and statistically based model that demonstrates a direct link between the proposed primary prevention intervention and any resulting TennCare cost savings derived by the prevention of opioid-exposed pregnancies;

(6) "Prevention service contractor" means an entity contracted to operate a statewide opioid baby primary prevention program using a pay for success program model;

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(7) "Primary prevention intervention" means a scripted, individual education and patient navigation session given to selected women that:

(A) Lasts at least fifteen (15) minutes;

(B) Is delivered in-person or via telemedicine by a PFS program counselor; and

(C) Is performed in cooperation with a prescribing physician or other clinical oversight;

(8) "Savings period" means the time that a TennCare MCO in the PFS program is realizing cost prevention savings derived from the program's service, and is spending less than budgeted on planned TennCare expenses from opioid-affected births and their related expenses; and

(9) "Selected woman" or "woman" means a woman of child-bearing age who:

(A) Has been prescribed an opioid for longer than thirty (30) days;

(B) Has delivered an opioid-affected infant; or

(C) Has been determined by the program rules to be at-risk for an opioid-affected birth.

(b) The bureau, in consultation with the comptroller, shall establish, by means of an amendment to an applicable contractor risk agreement, the contractual means for TennCare managed care organizations (MCOs) to operate a uniform statewide opioid baby primary prevention program to deliver a tailored educational service statewide to selected women in accordance with this section. The program shall be a pay for

success program and include education to the women regarding the risks of intrauterine drug exposure, education concerning their contraceptive options, and navigation to a provider of contraception if they so choose.

(c)

(1) The bureau shall institute an opioid baby primary prevention program utilizing a PFS program model. The bureau shall require MCOs participating in the TennCare program to begin the implementation of this program on or before January 1, 2018.

(2) The program shall provide that:

(A) An MCO participating in the TennCare program contract with a prevention service contractor in order to reduce the expense to the TennCare program of opioid-affected births and related expenses;

(B) The prevention service contractor must be able to perform, solely at its own expense, the primary prevention intervention statewide;

(C) The prevention service contractor shall only be paid for successful interventions that prevent opioid-affected births according to the amounts stipulated in the pay for success savings formula, and as verified by the independent third-party evaluator on a quarterly basis;

(D) The prevention service contractor must:

(i) Maintain HIPAA-compliance with respect to protected health information and comply with applicable federal and state rules concerning privacy and protected information;

(ii) Enter into business associate agreements; and

(iii) Establish data sharing arrangements with the bureau, the independent third-party evaluator, and the MCOs;

(E) Subject to a selected woman consenting to participate in the program, the primary prevention intervention must occur:

- (i) Prior to a prescription being written for opioids;
- (ii) Within a timeframe defined by existing state or federal rules and guidelines governing the prescription of opioids; or
- (iii) Within thirty (30) days of discovery of opioid exposure as defined by the program rules; provided, that, regardless of prescription status, any selected woman delivering an infant diagnosed as drug-exposed shall receive the intervention within one (1) week of delivery, if clinically feasible;

(F) For each selected woman participating in the program:

- (i) The prevention service contractor shall personally contact the woman and her prescribing provider every six (6) months to monitor for changes in the woman's status; and
- (ii) If the woman did not select a voluntary reversible long acting contraceptive method during her previous intervention the prevention service contractor shall repeat the intervention every six (6) months to ensure that continuing awareness of risk is maintained; and

(G) The net audited prevention savings for opioid-affected births and their related expenses identified by the evaluator and realized by the MCO shall be re-allocated to expand spending for increased substance abuse treatment programs within the TennCare program minus the amount paid to the prevention service contractor under the pay for success savings formula.

(d) The prevention service contractor shall bear all start-up and operation costs of the PFS program. Except for funds provided pursuant to the pay for success savings formula, no government funds shall be part of the PFS program. The PFS program shall not require an increase in the TennCare capitated rate to the MCOs, or require any new

spending by the MCOs beyond what is expected under the applicable current capitation rate.

(e) The PFS program shall be audited by an independent third-party evaluator who shall verify the success of the program in reducing opioid-affected birth expenses using predetermined objective measures as approved by the bureau and the comptroller. If the independent third-party evaluator determines that the prevention service contractor was successful in reducing TennCare expenses for opioid-affected births, a percentage of the savings, as approved by the bureau and the comptroller, shall be paid as a success fee to the prevention service contractor. The remaining savings shall be redirected as determined by the burden to TennCare clinical spending priorities for substance abuse treatment and other related TennCare expenses.

(f) The contraceptive education within the primary prevention intervention must meet state or federal rules and guidelines governing the prescribing physician's requirements from the United States department of health and human services for such education, as well as federal Title X Family Planning requirements for being broad-based, non-directive, and free from coercion, or other applicable federal and state rules.

(g) The primary prevention intervention must include a patient navigation service to assist the selected woman who chooses to access contraception to be referred to participating public or private medical providers who can prescribe the patient's chosen method of contraception. Patient navigation shall also assist, either directly or through local partners, in removing barriers to fulfillment such as transportation, priority scheduling, funding assistance, or other required aid as allowed under state and federal law.

(h) The primary prevention intervention must be digitally recorded via video and stored in a HIPAA-compliant form for quality assurance, federal Title X Family Planning compliance, and documentation of informed consent. The location and login information of the patient's individual video record must be provided to the prescribing physician or

clinic-of-record for insertion into the patient's electronic medical record and be available online for the woman's review at home.

(i)

(1) The comptroller, in consultation with the bureau, the MCOs, and the prevention service contractor shall select in accordance with title 12, chapter 4, an independent third-party evaluator from among nationally recognized and accredited accounting and auditing firms. The evaluator is responsible for independently verifying the validity of the pay for success savings formula, auditing the success of the prevention service contractor in reaching its measurable success outcomes, and other functions as determined by the program.

(2) The evaluator shall also audit, verify, and determine on a quarterly basis:

(A) The gross amount of opioid birth expenses successfully avoided by the program's interventions;

(B) Any success fees due the prevention service contractor; and

(C) The net amount of avoided opioid birth expenses to be redirected to other TennCare clinical spending priorities for substance abuse treatment or other related TennCare expenses.

(3) The pay for success formula shall explicitly provide a clinically measurable objective procedure for determining that a successful intervention has taken place, and the intervention's financial cost prevention savings value for expected TennCare expenses from opioid-affected births and their related expenses. The PFS program savings formula proposed by the prevention service contractor will be validated by the independent third-party evaluator in consultation with the bureau of TennCare and the MCOs. The comptroller shall approve any PFS program savings formula before it is applied in the program.

(j) The savings period shall continue until a selected woman meets one of the following conditions:

- (1) The woman is no longer exposed to opioids;
- (2) The woman is clinically determined to be unable to bear children; or
- (3) The woman has stopped using effective contraception.

(k) If the commissioner of finance and administration, in consultation with the bureau, determines that a federal waiver or an amendment to an existing federal waiver is necessary in order to implement this section, the commissioner shall promptly apply for an appropriate waiver or waiver amendment to the United States department of health and human services. If a waiver or waiver amendment is necessary, then this section shall not be implemented until six (6) months after the waiver or waiver amendment is approved.

SECTION 3. The bureau of TennCare is authorized to promulgate rules to effectuate the purposes of this act. The rules shall be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in Title 4, Chapter 5.

SECTION 4. This act shall take effect upon becoming a law, the public welfare requiring it.